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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,633	07/29/2003	Armin Breitenbach	6102-000068/US	9056

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,633	BREITENBACH ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18 and 20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/16/08 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 18 and 20-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-59 of copending Application No. 10/523908 ('908). Although the conflicting claims are not identical, they are not patentably distinct from each other because application '908 claimed a transdermal therapeutic system (TTS) comprising a drug-containing hot-melt adhesive matrix produced by metering the drug into the solvent-free melt of the adhesive matrix at a temperature of 102°C-160°C. The TTS further comprises a drug and a softener (claims 28 and 31). Hot-melt adhesive includes amine-resistant silicone (claim 31). Softeners are found in claims 32 and 33. Drug include Rotigotine is found in claims 28, 29 and 42-44. Amount of drug is found in claims 34-36. Drug present in form of a base is found in claim 37. Release profile is found in claims 46-48. Accordingly, the present claims are anticipated by the claims of the '908 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16, 18 and 20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that the specification does not provide support for the limitation "hydrophilic *and* amphiphilic polymers" and "hydrophilic *and* amphiphilic copolymers" in claim 10. It is noted that the present specification at page 15, discloses "hydrophilic **or** amphiphilic polymers" and "hydrophilic **or** amphiphilic copolymers". Further, while the specification discloses using a hot-melt process to prepare the claimed TTS (paragraphs 0034 and 0107-0113), the specification, however, does not appear to provide support for the limitation "active substance is…melted using a hot-melt process".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16, 18 and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the phrase "the active substance is dispersed and partly or completely dissolved and melted using a hot-melt process" in lines 3-4, is confusing. It is not entirely sure what it means in this context, whether the active agent is dispersed, dissolved or melted?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-16, 18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US 5,807,570, in view of Metman et al. (Clinical Neuropharmacology) and Loper et al. US 4,880,633.

Chen teaches a TTS comprising a backing layer, and an adhesive polymeric matrix which contains combination of a permeation enhancer and at least about 30% ropinirole or an analog thereof as an active agent (abstract; column 3, lines 1-37; column 4, lines 25-37; and column 6, lines 36-46). Permeation enhancer includes polyethylene glycol, propylene glycol, alcohol, and the like (column 7, lines 24-39). Active agent can be administered in the form of a base or pharmaceutically acceptable salt (column 7, lines 6-10). The polymeric matrix further comprises pressure sensitive adhesive polymer including silicone (column 8, lines 48-67).

Chen does not expressly teach the claimed active agent.

Metman teaches transdermally administering rotigotine for the treatment of Parkinson's disease (abstract). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen to include rotigotine as an active agent in view of the teaching of Metman, because Metman teaches that rotigotine is an effective treatment for advanced Parkinson's disease with mild adverse effects compare to other

active agent, because Metman teaches using rotigotine for the treatment of Parkinson's disease allows patients to substantially lower L-Dopa doses without loss of antiparkinsonian efficacy, and because Chen teaches the desirability to obtain a TTS useful for the treatment of Parkinson's disease.

Chen is silent with respect to the teaching of hot-melt process.

Loper teaches a transdermal drug delivery system comprising a drug reservoir matrix. The drug reservoir matrix is coated onto the backing layer using hot melt deposition process (column 8, lines 18-36). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen using the hot-melt deposition process of Loper to obtain the claimed invention. This is because Loper teaches hot melt process is well known in the art, because Loper teaches using hot melt process as an alternative process to deposit the drug reservoir matrix onto the backing layer, and because Chen teaches the desirability for obtaining a TTS having a drug reservoir matrix.

Claims 1-16, 18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US 5,807,570, in view of Metman et al. (Clinical Neuropharmacology) and Loper et al. and Noel. US Re. 36,754

Chen is relied upon for the reason stated above. Chen further does not teach the matrix system that comprises organic wax.

Noel teaches a hot-melt silicone-base TTS comprising silicone sensitive adhesive, and organic waxes having melting point between 30-150°C (abstract).

Organic waxes include vegetable waxes, animal waxes, mineral waxes such as ozokerite, and mixtures thereof in an amount of from about 1 to about 25% (column 5, lines 1-11; and claim 17). Silicone sensitive adhesive is present in an amount from about 99-85% (column 8, lines 41-44). Noel further teaches the hot-melt silicone-base TTS is free of solvent (column 2, lines 66-67). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen using the hot-melt silicone-base TTS in view of the teaching of Noel to obtain the claimed invention. This is because Noel teaches a transdermal system that is highly efficacious, because Noel teaches using organic waxes to decrease viscosity and improve coatability which do not require the present of solvents (column 1, lines 66 through column 2, lines 1-3), because Noel teaches using organic waxes over the use of solvents to avoid: 1) removal and containment of solvents, 2) special precautions to avoid fires, and 3) cost effectiveness (ID), because Chen teaches a TTS that comprises silicone and waxes as carriers (column 6, lines 25-27), and because Chen teaches the desirability to obtain a TTS that improved patient compliance and with less side effects (column 2, lines 51-60).

Response to Arguments

Applicant's arguments filed 09/16/08 have been fully considered but they are not persuasive.

Applicant states that Applicant may elect to argue to overcome the provisional obviousness-type double patenting rejection or to provide a terminal disclaimer (to the

extent necessary) once the present claims have been found to be otherwise allowable and/or once the co-pending application issues as a patent.

Accordingly, the rejection is maintained.

The 112, first paragraph scope of enablement rejection has been withdrawn in view of the amendment filed 09/16/08, changing the dependency of claim 14 to depend in claim 12.

Applicant argues that claim 10 is written in Markush form in which the linking conjunction "and" is proper. Paragraph [0076] of the specification as filed discloses options for the internal-phase components including:

(a) hydrophilic or amphiphilic polymers,

(b) hydrophilic or amphiphilic copolymers,

(c) mixtures of (a) and/or (b) with pharmaceutically acceptable softeners, *etc.*

These components are properly recited in Claim 10 as "selected from the group consisting of (a) hydrophilic and amphiphilic polymers and mixtures thereof with pharmaceutically acceptable softeners, (b) hydrophilic and amphiphilic copolymers and mixtures thereof with pharmaceutically acceptable softeners," *etc.* Nothing in the present specification limits the meaning of the conjunction "or" as used in paragraph [0076] to exclude the presence of both hydrophilic and amphiphilic types; likewise *"an* internal-phase component selected from the group consisting of hydrophilic and amphiphilic" types is to be read as a proper Markush recitation in which either one of the

two types, or both, is present. Withdrawal of the present rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

However, in response to applicant's argument that *"nothing in the present specification limits the meaning of the conjunction "or" as used in paragraph [0076] to exclude the presence of both hydrophilic and amphiphilic types; likewise "an internal-phase component selected from the group consisting of hydrophilic and amphiphilic" types is to be read as a proper Markush recitation in which either one of the two types, or both, is present"*, the examiner is unable to understand applicant's analysis, because the present specification clearly discloses (a) hydrophilic ***or*** amphiphilic copolymer, (b) hydrophilic ***or*** amphiphilic copolymer. Assuming the Markush language disclosed in paragraph 0076 is proper, the selection is among components (a), (b), (c), and (d), wherein (a) is hydrophilic ***or*** amphiphilic copolymer, (b) is hydrophilic ***or*** amphiphilic copolymer, and (c) is mixture of (a) and (b). Nowhere in the specification discloses (a) is (a) hydrophilic and amphiphilic copolymer, (b) hydrophilic and amphiphilic copolymer, as recited in claim 10. Accordingly, the rejection is maintained.

Applicant's arguments with respect to claims 1-16, 18 and 20-25 under the 103(a) rejection by Chen, in view of Metman and Noel have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615